Docket No. 4705-0120PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Heno PERILLO et al.

Application No. 10/580,651 — Confirmation No. 5789

Filed: November 29, 2006 — Art Unit: 1614

For: READY-FOR-USE INJECTABLE SOLUTION OF 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE, STERILE, STABLE; CLOSED SYSTEM FOR PACKING THE SOLUTION, PROCESS FOR ELIMINATING ALKALINE RESIDUALS OF 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6 (9H)-ONE CRYSTALS; PHARMACEUTICAL PRESENTATION AS A CLOSED SYSTEM READY-FOR-USE; USES AND METHODS

Examiner: FINN, M.R.

PETITION TO EXTEND PERIOD OF SUSPENSION OF ACTION UNDER 37 CFR 1.103(A)

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

May 27, 2011

Sir:

Applicants respectfully petition for extension of the originally requested period of suspension of action in the above-referenced application for an additional three month period, to August 28, 2011. This request is made for good cause, as Applicants have used the present period of suspension to arrange for and begin comparative experiments to demonstrate unobviousness of the present invention over prior art cited by the Examiner.

Statement of facts in support of petition

1. On December 11, 2009, the Examiner issued an Office Action rejecting claims 44-46 of the present application under 35 USC § 103(a) over Smith '475, Harris '258 and Muller '776.

2. On June 11, 2010, Applicants responded to the Office Action with arguments and a Declaration of Mr. Perillo.

3. On August 31, 2010, the Examiner issued a Final Office Action, maintaining the rejection of claims 44-46 and explaining that the Perillo Declaration was insufficient to overcome the rejection as it did not include a side-by-side comparison of gangcyclovir as described by the instant claims and that described by Smith et al. and commercially available gangcyclovir.

4. On December 9, 2010 a telephone interview was conducted with the Examiner, to discuss the kind of comparative testing that might be found persuasive.

5. On February 28, 2011, Applicants filed a Request for Continued Examination, including a Request for Suspension of Action for a period of three months to allow for the recommended comparative testing. The RCE filed was deemed formally deficient due to inadvertent omission of a paper, but those deficiencies were ultimately addressed and the application remains presently pending and under suspension of action until May 28, 2011.

6. During the period of suspension, Applicants have made arrangements with a contractor to perform the recommended comparative testing. Conduct of the experiments has been somewhat delayed by the making of these arrangements.

7. The experiments are now underway and the following timetable sets forth the plan of experimentation to be conducted:

25/04/2011 - 17/06/2011 (40 days) - Reproduction of the gancyclovir described by Smith et al.

17/06/2011 - 28/07/2011 (30 days) - TGTDG and DSC Thermal analysis of samples of commercially available Gancyclovir, Gancyclovir of the present invention, Gangcyclovir produced according to Smith and sodium Gancyclovir.

11/07/2011 - 19/08/2011 (30 days) - X-ray Diffraction Comparative Analysis of samples as set forth above.

17/08/2011 - 25/08/2011 (5 days) - Report Preparation by the contractor and return of the report to Applicants.

8. As can be seen from this timetable, Applicants expect to be able to resume prosecution of the present application by August 28, 2011.

Statement of relief requested

Applicants hereby request extension of the present period of suspension of action for an additional three months, from May 28, 2011 to August 28, 2011.

Applicants submit that the relief requested is made for good cause, in that comparative testing recommended by the Examiner is taking longer than the original three month period initially requested, at least in part due to delay arising from the need to make contract arrangements for the experimentation. Experimentation has begun and is expected to be completed within the extended time period requested herein.

Fees

The fee of $200 required by 37 CFR 1.17(g) is attended to by the Fee Transmittal attached hereto.

Should there be any outstanding matters that need to be solved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in the connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.R.F. §§1.16 or 1.14; particularly, extension of time fees.

Dated: May 27, 2011

Respectfully submitted,

By _____
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